

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

_____	)	
WYETH, a Delaware corporation,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	C.A. No. 06-663-SLR
	)	
CORDIS CORPORATION, a Florida	)	<b>REDACTED</b>
corporation,	)	<b>PUBLIC VERSION</b>
	)	
Defendant.	)	
_____	)	

**APPENDIX (VOLUME V – MISCELLANEOUS) TO  
PLAINTIFF WYETH’S ANSWERING BRIEF IN OPPOSITION  
TO DEFENDANT CORDIS CORPORATION’S “MOTION TO DISMISS PURSUANT  
TO FEDERAL RULE OF CIVIL PROCEDURE 12(b)(1) OR, IN THE ALTERNATIVE,  
TO DISMISS OR STAY THIS ACTION PENDING RESOLUTION OF THE  
CO-PENDING ACTION IN THE DELAWARE COURT OF CHANCERY”**

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Original Filing Date: February 12, 2007  
Redacted Filing Date: February 20, 2007

**VOLUME V TABLE OF EXHIBITS**

<b>Exhibit</b>	<b>Description</b>
45	Guidant Corporation's Form 10-Q for the quarterly period ended March 31, 2004, Ex. 10.28 (May 7, 2004)
46	[REDACTED]
47	Stipulation Letter from Rosa E. Son, counsel for Cordis, to Tracey C. Allen, counsel for Wyeth (Feb. 1, 2007)
48	[REDACTED]
49	[REDACTED]
50	[REDACTED]

# EXHIBIT 45

10-Q 1 q1\_10q.htm

SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

**FORM 10-Q**

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended **March 31, 2004**

Commission File Number **1-13388**

**GUIDANT CORPORATION**  
(Exact name of Registrant as specified in its charter)

**INDIANA**  
(State or other jurisdiction of  
incorporation or organization)

**35-1931722**  
(I.R.S. Employer  
Identification No.)

**111 MONUMENT CIRCLE, 29TH FLOOR**  
**INDIANAPOLIS, INDIANA 46204-5129**  
(Address of principal executive offices)

Registrant's telephone number, including area code: **(317) 971-2000**

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒ No ☐

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act).

Yes ☒ No ☐

The number of shares of common stock outstanding as of May 5, 2004:

<u>Class</u>	<u>Number of Shares Outstanding</u>
Common	313,658,957

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**PART I**  
**FINANCIAL INFORMATION**

**Item 1. Financial Statements**

**GUIDANT CORPORATION**  
**Consolidated Statements of Income**  
(In millions, except per share data)  
(unaudited)

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	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2004</b>	<b>2003</b>
Net sales	\$ 934.1	\$ 857.9
Cost of products sold	226.3	205.1
Gross profit	707.8	652.8
Research and development	137.6	112.8
Purchased in-process research and development	26.8	36.5
Sales, marketing and administrative	314.7	269.0
Interest, net	(1.0)	(1.4)
Royalties, net	12.1	13.3
Amortization	7.3	3.2
Other, net	2.5	5.3
Income from continuing operations before income taxes	207.8	214.1
Income taxes	54.8	57.7
Income from continuing operations	153.0	156.4
Loss from discontinued operations, net of income taxes	(13.6)	(63.0)
Net income	\$ 139.4	\$ 93.4
Earnings per share - basic		
Income from continuing operations	\$ 0.50	\$ 0.52
Loss from discontinued operations, net of income taxes	(0.05)	(0.21)
Net income	\$ 0.45	\$ 0.31
Earnings per share - diluted		
Income from continuing operations	\$ 0.48	\$ 0.51
Loss from discontinued operations, net of income taxes	(0.04)	(0.21)
Net income	\$ 0.44	\$ 0.30
Dividends declared per common share	\$ 0.10	\$ 0.08

See Notes to Consolidated Financial Statements

**GUIDANT CORPORATION**  
**Consolidated Balance Sheets**  
*(In millions, except share data)*

	<b>March 31,</b>	<b>December 31,</b>
	<b>2004</b>	<b>2003</b>
	<i>(unaudited)</i>	
<b>Assets</b>		
<b>Current Assets</b>		
Cash and cash equivalents	\$1,612.3	\$1,468.2
Accounts receivable, net of allowances of \$25.0 (2004) and \$24.0 (2003)	799.7	822.9
Inventories	414.9	401.9
Deferred income taxes	302.4	313.2
Prepaid expenses and other current assets	71.5	57.7

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See Notes to Consolidated Financial Statements

### Liabilities and Shareholders' Equity

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Deferred cost, ESOP	(16.0)	(17.1)
Unearned compensation	(10.1)	(25.2)
Treasury stock, at cost:		
Shares: 313,739 (2004)		
3,158,000 (2003)	(21.2)	(171.2)
Accumulated other comprehensive income	110.7	124.0
	<hr/>	
Total Shareholder's Equity	2,984.8	2,713.3
	<hr/>	
Total Liabilities and Shareholders' Equity	\$ 4,818.3	\$ 4,640.1
	<hr/>	

See Notes to Consolidated Financial Statements

**GUIDANT CORPORATION**  
**Consolidated Statements of Cash Flows**  
*(In millions)*  
*(unaudited)*

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2004</b>	<b>2003</b>
<b>Operating Activities</b>		
Net income	\$ 139.4	\$ 93.4
Adjustments to Reconcile Net Income to Cash Provided by Operating Activities:		
Depreciation	34.6	31.1
Amortization of other intangible assets	7.3	3.4
Provision for inventory and accounts receivable	4.4	14.9
Purchased in-process research and development	26.8	36.5
Deferred income taxes	24.9	(26.5)
Compensation earned under restricted stock and ESOP	28.1	19.3
Other noncash, net	21.8	(13.0)
	287.3	159.1
<b>Changes in Operating Assets and Liabilities:</b>		
Receivables	(0.8)	(5.6)
Inventories	(19.0)	(22.6)
Prepaid expenses and other current assets	(22.4)	(3.1)
Accounts payable and accrued liabilities	(77.5)	(57.4)
Income taxes payable	(24.8)	60.3
Other liabilities	(11.6)	(20.4)
	131.2	110.3
<b>Net Cash Provided by Operating Activities</b>	131.2	110.3
<b>Investing Activities</b>		
Additions of property and equipment, net	(57.9)	(33.5)
Acquisition of business, net of cash acquired	(48.4)	--
Investment purchases	(5.4)	(1.5)
Additions of other assets, net	(1.0)	(0.6)
Purchase of in-process research and development	(1.1)	(17.7)
	(113.8)	(53.3)
<b>Net Cash Used for Investing Activities</b>	(113.8)	(53.3)
<b>Financing Activities</b>		
Increase in borrowings, net	76.9	1.3
Issuance of common stock under stock plans and other capital transactions	186.3	8.5

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Dividends paid	(31.0)	--
Repurchase of common stock	(97.5)	(0.3)
<b>Net Cash Provided by Financing Activities</b>	<b>134.7</b>	<b>9.5</b>
Effect of Exchange Rate Changes on Cash	(8.0)	23.7
<b>Net Increase in Cash and Cash Equivalents</b>	<b>144.1</b>	<b>90.2</b>
Cash and Cash Equivalents at Beginning of Period	1,468.2	1,014.8
<b>Cash and Cash Equivalents at End of Period</b>	<b>\$ 1,612.3</b>	<b>\$ 1,105.0</b>

See Notes to Consolidated Financial Statements

**GUIDANT CORPORATION**  
**Notes to Consolidated Financial Statements**  
*(In millions, except per share data)*  
*(unaudited)*

**Note 1 – Basis of Presentation**

The accompanying unaudited consolidated financial statements have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. Operating results from interim periods are not necessarily indicative of results that may be expected for the fiscal year as a whole. In the opinion of management, the consolidated financial statements reflect all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation of the Company's results for the periods presented. The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and related disclosures at the date of the financial statements and during the reporting period. Actual results could differ from these estimates. A discussion of the Company's significant accounting policies is described in the "Significant Accounting Policies" section of "Management's Discussion and Analysis of Results of Operations and Financial Condition."

For further information, refer to the consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2003. As used herein, the terms "the Company" and "Guidant" mean Guidant Corporation and its consolidated subsidiaries.

Certain reclassifications have been made to prior year amounts to conform to current year presentation (see Note 9).

**Note 2 – Stock-Based Compensation**

The Company has adopted the disclosure-only provisions of Statement of Financial Accounting Standard ("SFAS") 123, *Accounting for Stock-Based Compensation*, as amended by SFAS 148, *Accounting for Stock-Based Compensation—Transition and Disclosure*. Accordingly, the Company accounts for stock-based compensation under Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*, and related interpretations, using the intrinsic value method. The following table illustrates the effect on net income and earnings per share if the Company had applied the fair value recognition provisions of SFAS 123 to all stock-based employee compensation. The fair value of stock options was estimated as of the grant date using the Black-Scholes option-pricing model, the attribution method and a forfeiture rate of 10%. The Black-Scholes option-pricing model does not consider the non-traded nature of employee stock options, the lack of transferability or a vesting period. If the model took these items into consideration, the resulting estimate for fair value of the stock options could be different. These pro forma amounts may not be representative of the effects on reported net income for future years due to the uncertainty of stock option grant volume and potential changes in assumptions driven by market factors.

Three Months Ended

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	<b>March 31,</b>	
	<b><u>2004</u></b>	<b><u>2003</u></b>
Reported net income (1)	\$ 139.4	\$ 93.4
Deduct: Stock-based compensation not reflected in net income, net of tax	10.4	15.8
Pro forma net income	<u>\$ 129.0</u>	<u>\$ 77.6</u>
Earnings per share:		
Basic--as reported	<u>\$ 0.45</u>	<u>\$ 0.31</u>
Basic--pro forma	<u>\$ 0.42</u>	<u>\$ 0.26</u>
Diluted--as reported	<u>\$ 0.44</u>	<u>\$ 0.30</u>
Diluted--pro forma	<u>\$ 0.40</u>	<u>\$ 0.25</u>

(1) Reported amounts include expense associated with restricted stock awards.

## GUIDANT CORPORATION

### Notes to Consolidated Financial Statements

#### Note 2 – Stock-Based Compensation (continued)

In February 2003, Guidant's Board of Directors authorized the issuance of approximately 2.3 million restricted stock awards to over 2,000 employees. Restricted stock awards are expensed ratably over the vesting period. This grant included a performance element that allowed vesting to accelerate when certain Guidant share price performance measures were met. Specifically, 1/3 of the general grants vested upon achievement of 25%, 50% and 75% appreciation of the 60-day moving average stock price from the date of grant (\$34.37 on February 18, 2003). Executive officer grants accelerated from six years to three years under this same performance measure. Approximately two-thirds of the share price appreciation targets were achieved and expensed in 2003. Grants may vest earlier upon a qualifying disability, death, retirement or change in control. The final share price appreciation target (75%) was achieved in January 2004 and resulted in additional expenses in the first quarter of 2004 of \$14.7 million.

On April 1, 2004, Guidant granted approximately 3.1 million stock options and 610,000 restricted stock awards to over 2,500 employees. Under this program, stock options will vest ratably over three years and the restricted stock awards will vest on April 1, 2007. For certain executive officers, the restricted stock awards vest over six years, but may be accelerated to three-year vesting, 1/3 of the grant will vest upon achievement of 25%, 50% and 75% appreciation of the 60-day moving average stock price from the date of grant (\$63.11 on April 1, 2004). Grants may vest earlier upon a qualifying disability, death, retirement or change in control.

#### Note 3 – Inventories

Inventories consisted of the following:

	<b>March 31, 2004</b>	<b>December 31, 2003</b>
Finished products	\$189.4	\$172.9
Work in process	77.6	81.5
Raw materials and supplies	147.9	147.5
	<u>\$414.9</u>	<u>\$401.9</u>

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**Note 4 – Product Warranties**

Provisions for estimated expenses related to product warranties are recorded at the time the products are sold. Estimates for warranty costs are calculated based primarily upon historical warranty experience, but may include assumptions related to anticipated changes in warranty costs and failure rates. A summary of the changes in the product warranty activity is as follows:

	<b>Three Months Ended March 31,</b>	
	<b>2004</b>	<b>2003</b>
January 1	\$ 22.3	\$ 18.8
Provisions for product warranties	0.6	1.7
Settlements during the period	(4.2)	(1.8)
March 31	<u>\$ 18.7</u>	<u>\$ 18.7</u>

**GUIDANT CORPORATION**  
**Notes to Consolidated Financial Statements**

**Note 5 – Earnings Per Share**

The following table sets forth the computation of earnings per share:

	<b>Three Months Ended March 31,</b>	
	<b>2004</b>	<b>2003</b>
Income from continuing operations	\$ 153.0	\$ 156.4
Loss from discontinued operations, net of income taxes	(13.6)	(63.0)
Net income	<u>\$ 139.4</u>	<u>\$ 93.4</u>
<b>Earnings per share--basic</b>		
Income from continuing operations	\$ 0.50	\$ 0.52
Loss from discontinued operations, net of income taxes	(0.05)	(0.21)
Net income	<u>\$ 0.45</u>	<u>\$ 0.31</u>
<b>Earnings per share--diluted</b>		
Income from continuing operations	\$ 0.48	\$ 0.51
Loss from discontinued operations, net of income taxes	(0.04)	(0.21)
Net income	<u>\$ 0.44</u>	<u>\$ 0.30</u>
Weighted average common shares outstanding	308.48	303.20
Effect of dilutive stock options and unvested restricted stock awards (1)	10.08	4.83
Weighted average common shares outstanding and assumed conversions	<u>318.56</u>	<u>308.03</u>

(1) Increase is primarily due to the appreciation of Guidant's average stock price for the quarter ending March 31, 2004, compared to the quarter ending March 31, 2003.

Total options outstanding at March 31, 2004 and 2003 were 39.6 million and 49.7 million. Earnings per share-diluted includes 39.5 million and 20.3 million stock options for the quarters ended March 31, 2004 and 2003. Stock options whose

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exercise price per share was greater than their average market value per share were excluded from the calculation of earnings per share-diluted because including them would have had an anti-dilutive impact.

#### Note 6 – Comprehensive Income

Comprehensive income is comprised of net income adjusted for changes in foreign currency translation adjustments and unrealized gains or losses on foreign currency derivative contracts designated and qualifying as cash flow hedges. For the first quarters of 2004 and 2003, comprehensive income was \$126.2 million and \$114.3 million. The increase in comprehensive income was primarily due to higher net income in 2004, partially offset by foreign currency translation losses in 2004 compared to gains in 2003.

### GUIDANT CORPORATION

#### Notes to Consolidated Financial Statements

#### Note 7 – Segment Information

##### Geographic Information:

	Three Months Ended March 31,	
	<u>2004</u>	<u>2003</u>
Net Sales(1):		
US	\$616.8	\$593.2
International	317.3	264.7
	<u>\$934.1</u>	<u>\$857.9</u>

(1) Revenues are attributed to countries based on location of the customer.

	March 31, <u>2004</u>	December 31, <u>2003</u>
Long-lived Assets:		
US	\$684.5	\$660.8
International	87.6	88.3
	<u>\$772.1</u>	<u>\$749.1</u>

	Three Months Ended March 31,	
	<u>2004</u>	<u>2003</u>
Classes of Similar Products:		
Net Sales:		
Implantable defibrillator systems	\$ 405.0	\$ 332.0
Pacemaker systems	179.5	159.2
Coronary stent systems	171.4	221.0
Angioplasty systems	116.6	99.6
Cardiac surgery, biliary, peripheral and carotid systems	61.6	46.1

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\$ 934.1	\$ 857.9
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#### Note 8 – Acquisitions

**AFx, inc.:** On February 9, 2004, Guidant acquired AFx, inc., a manufacturer of microwave surgical cardiac ablation medical devices. Guidant paid \$48.4 million (including transaction expenses) in cash and forgave a \$5.8 million extension of credit. The purchase price was allocated to the acquired assets and liabilities based upon fair market values (using the income approach), including a \$22.8 million in process research and development (IPRD) charge for technology that had not reached technological feasibility and had no alternative use and \$33.0 million for intangible assets related to proven technology. In addition, a deferred tax liability was recorded for the tax effect of the intangible assets and deferred tax assets of \$11.7 million were recorded for the net operating loss carryovers expected to be utilized in the future by Guidant. In order to value the IPRD, a risk-adjusted discount rate of 22.5% was applied to the cash flows, which are expected to begin during the second quarter of 2005. Guidant may make additional payments upon future satisfaction of regulatory, clinical and sales performance criteria. These payments will be recorded when the amount is determinable and will be allocated to the fair value of the intangibles or IPRD, with any amounts paid above fair value of identifiable assets recorded as goodwill.

**Biosensors International:** In March 2003, the Company completed its acquisition of certain assets of Biosensors International's (Biosensors) everolimus eluting stent program, including an exclusive worldwide license to Biosensors' polymer formulation technology in the field of everolimus eluting stents and a nonexclusive license to use this technology with other drugs in drug eluting stents. Additionally, Guidant acquired the option of manufacturing and commercializing the Biosensors everolimus eluting stent that has been used in Biosensors' clinical trials. Guidant recorded a \$20.5 million IPRD charge in connection with the purchase, since technological feasibility of the project has not been attained and the research has no alternative future uses. Biosensors may receive additional milestone payments over the course of clinical development and upon CE Mark approval. In addition, Biosensors will receive royalties on future sales of products utilizing Biosensors' technology.

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**Bioabsorbable Vascular Solutions:** In March 2003, Guidant acquired the majority interest in Bioabsorbable Vascular Solutions (BVS) for \$10.0 million and accrued an additional \$6.0 million for a future milestone. In addition, Guidant purchased the remaining interest for \$6.0 million in April 2004. All these amounts are accounted for as IPRD, since technological feasibility of the project has not been attained and the research has no alternative future uses. BVS is developing vascular stent platforms designed to be absorbed by tissue following the restoration of blood flow in patients with coronary artery disease. Guidant may pay milestone payments over the course of clinical development.

Certain of Guidant's acquisitions involve contingent consideration. Payment of the additional consideration is generally contingent upon reaching performance-related milestones, including specified revenue levels, product development targets or regulatory approvals or filings. At March 31, 2004, Guidant's accrual for milestone obligations totaled \$8.3 million and will be paid during the next three years. In addition, future undiscounted contingent consideration for performance-related milestones on acquisitions of up to \$465.0 million could be paid through 2010, depending on when and if milestones are attained. Potential milestone payments under existing agreements during the next 12 months range from \$6.0 to \$118.0 million. The Company continues to evaluate business development opportunities, which may generate additional payments.

The operating results of all acquisitions are included in the Company's consolidated financial statements from the date of each acquisition.

#### Note 9 – Discontinued Operations

In March 2004, Guidant's Board of Directors approved a plan to discontinue the GALILEO® Intravascular Radiotherapy System (GALILEO System) product line for the treatment of in-stent restenosis due to the significant competitive impact of drug eluting stents. On April 21, 2004, Guidant signed a definitive agreement with Novoste Corporation (Novoste) to cooperate in assisting existing US and Canadian customers of the GALILEO System who wish to transition to Novoste products. Guidant received \$2.5 million upon signing and will receive earn-out payments up to a maximum of \$4.0 million based on Novoste sales in the US and Canada. The disposal plan consists primarily of the termination of normal activity, abandonment of property and equipment, product returns, collection of accounts receivable and settlement of liabilities. Net loss from discontinued operations includes a charge of \$11.2 million during the quarter ended March 31, 2004, primarily

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related to the write down of long-lived assets to fair value and recording inventory and accounts receivable at net realizable value. Guidant expects this discontinuation to occur in several phases, concluding within the next six to nine months. Following a brief transition period, Guidant will close its Houston and Pearland, Texas, facilities.

In June 2003, Guidant's Board of Directors approved a plan to dispose of the ANCURE ENDOGRAFT System product line to treat abdominal aortic aneurysms (AAA) due to continuing financial losses, limited prospects for the Company's AAA product line and the impact of the Department of Justice investigation.

In addition, Guidant's Board of Directors ratified a plan in December 2003 to discontinue Guidant's operations in Brazil due to unfavorable business conditions and poor operating performance.

In accordance with SFAS 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, these disposals represent discontinued operations. Accordingly, the accompanying consolidated financial statements and notes reflect the results of operations and financial position of the AAA and GALILEO product lines and the Brazil operations as discontinued operations for all periods presented. Net loss from discontinued operations includes charges related to the impairment of certain long-lived assets, inventory write-downs, customer returns and accruals for employee severance and lease commitments. Net loss from discontinued operations in 2003 also includes charges related to litigation settlements.

At March 31, 2004, and December 31, 2003, there were \$13.5 million and \$36.5 million in assets and \$20.7 million and \$23.9 million in liabilities related to discontinued operations. Assets are primarily comprised of accounts receivable, inventory and property, plant and equipment. Liabilities primarily include accruals for severance, product returns and lease commitments.

The following summarizes financial information for discontinued operations:

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b><u>2004</u></b>	<b><u>2003</u></b>
Net sales	\$11.3	\$27.5
Loss from discontinued operations before income taxes	21.1	64.0
Net loss from discontinued operations	13.6	63.0

#### **Note 10 – Dividend**

On February 17, 2004, Guidant's Board of Directors declared a first quarter 2004 dividend of \$0.10 per common share outstanding which was paid March 15, 2004, to shareholders of record on March 1, 2004, compared to \$0.08 per common share for the first quarter of 2003.

#### **Note 11 – Contingencies**

A discussion of the Company's policies with respect to legal proceedings and other loss contingencies is described in the "Significant Accounting Policies" section of "Management's Discussion and Analysis of Results of Operations and Financial Condition." The description of legal proceedings in Part II, Item 1 ("Legal Proceedings") to this filing is incorporated herein by reference.

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#### **Item 2. Management's Discussion and Analysis of Results of Operations and Financial Condition** *(unaudited)*

Guidant Corporation provides innovative, therapeutic medical solutions of distinctive value for customers, patients and healthcare systems around the world. Guidant's lifesaving medical technologies are designed to extend the lives and improve the quality of life of millions of patients suffering from life-threatening cardiac and vascular disease. Approximately 12,000 employees develop, manufacture and market the Company's medical devices in nearly 100 countries, with key operations in the US, Europe and Asia. As used herein, the terms "the Company" and "Guidant" mean Guidant Corporation and its consolidated subsidiaries.

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Cardiovascular disease is the leading cause of death for both men and women in the US today and claims more lives each year than the next five leading causes of death combined. Within cardiovascular disease, Guidant develops, manufactures and markets products that focus on the treatment of coronary arrhythmias, heart failure, coronary artery disease and biliary and artery disease including:

- o Implantable defibrillator systems used to detect and treat abnormally fast heart rhythms (tachycardia) that could result in sudden cardiac death (SCD), including implantable cardiac resynchronization therapy defibrillator (CRT-D) systems used to treat heart failure
- o Implantable pacemaker systems used to manage slow or irregular heart rhythms (bradycardia), including implantable cardiac resynchronization therapy pacemaker (CRT-P) systems used to treat heart failure
- o Coronary stent systems for the treatment of coronary artery disease
- o Angioplasty systems including dilatation catheters and related accessories for the treatment of coronary artery disease
- o Cardiac surgery systems and biliary, peripheral and carotid systems used to treat biliary and peripheral artery disease

In March 2004, the Company decided to discontinue the GALILEO® Intravascular Radiotherapy System (GALILEO System) product line. This product line is reflected as a discontinued operation for all periods presented.

#### Operating Results — Three Months Ended March 31, 2004

##### Sales

Guidant reported \$934.1 million in worldwide sales for the quarter ended March 31, 2004, representing 9% growth compared to the same period in 2003. Growth in unit volume favorably impacted sales by 8%, partially offset by price declines of 3%. The impact of fluctuations in foreign currency exchange rates increased sales by \$32.9 million, or 4%. The Company's hedging policy serves to mitigate the impact of foreign currency exchange rate fluctuations on net income and therefore the impact in the first quarter 2004 was insignificant. US sales of \$616.8 million grew 4% over the prior year and international sales of \$317.3 million increased 20% (8% in constant currency).

##### Sales Summary—Three Months Ended

(In millions)	March 31, 2004			March 31, 2003			Growth
	US	Int'l.	Total	US	Int'l.	Total	
Implantable defibrillator systems	\$323.7	\$ 81.3	\$405.0	\$273.0	\$ 59.0	\$332.0	22%
Pacemaker systems	104.2	75.3	179.5	101.7	57.5	159.2	13%
Coronary stent systems	86.2	85.2	171.4	134.4	86.6	221.0	(22%)
Angioplasty systems	54.0	62.6	116.6	47.0	52.6	99.6	17%
Cardiac surgery, biliary, peripheral and carotid systems	48.7	12.9	61.6	37.1	9.0	46.1	34%
	\$616.8	\$317.3	\$934.1	\$593.2	\$264.7	\$857.9	9%

##### Implantable Defibrillator Systems

Worldwide sales of implantable defibrillator systems in the first quarter of 2004 were \$405.0 million, an increase of 22% over the same period in 2003. Growth was driven by increased implantable defibrillator volume including a shift toward higher-value CRT-D systems. US implantable defibrillator system sales increased 19% to \$323.7 million and international sales increased 38% (22% in constant currency) to \$81.3 million in the first quarter of 2004 compared to the same period in



the prior year. Implantable defibrillator systems sales growth was driven by:

- o Increased awareness for implantable defibrillator and cardiac resynchronization therapies based upon the findings of two Guidant-sponsored clinical trials — the pivotal MADIT II and COMPANION. MADIT II demonstrated that a broader group of patients would benefit from implantable defibrillator therapy and the investigators for the COMPANION Trial recently reported that for advanced heart failure patients with desynchronized heart contractions, the addition of resynchronization therapy to optimal drug treatment reduced the combination of death or hospitalization when compared with optimal drug treatment alone.
- o VITALITY® family of implantable defibrillator systems
- o CONTAK® RENEWAL™ family of CRT-D systems

In April 2004, Guidant announced FDA approval for the VITALITY 2 implantable defibrillator system. This device incorporates Guidant's RHYTHM ID™ feature, which utilizes rhythm discrimination technology to distinguish between lethal and non-lethal heart rhythms to deliver the appropriate care.

The National Heart, Lung and Blood Institute's Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT) has been completed, and the clinical trial results were presented in March 2004 at the American College of Cardiology Annual Scientific Session. The results demonstrated positive benefits of implantable defibrillators (reducing death by 23 percent versus patients who did not receive defibrillators) in patients with heart failure. The Centers for Medicare & Medicaid Services has indicated that it may consider the SCD-HeFT results as evidence to further expand reimbursement coverage for implantable defibrillators. Guidant formally joined in support of the petition to CMS for full SCD-HeFT patient population ICD coverage. The publication of SCD-HeFT and COMPANION clinical trial results and the related reimbursement decisions may impact the implantable defibrillator market.

#### Pacemaker Systems

Worldwide pacemaker system sales were \$179.5 million for the quarter ended March 31, 2004, a 13% increase over the same period in the prior year. US pacemaker system sales grew 3% to \$104.2 million and international sales grew 31% (19% in constant currency) to \$75.3 million for the first quarter of 2004 compared to the same period in 2003. Pacemaker system sales growth was driven by:

- o Continued acceptance of the INSIGNIA™ family of pacemaker systems
- o Broad acceptance of the CONTAK RENEWAL TR 2 CRT-P system, launched in the third quarter of 2003 in Europe and the CONTAK RENEWAL TR CRT-P system launched in the US in January 2004

#### Coronary Stent Systems

Worldwide coronary stent system sales for the first quarter of 2004 were \$171.4 million, a decline of 22% compared to the first quarter of 2003. The decline in sales was primarily driven by increasing penetration of competitive drug eluting stents in the US. Coronary stent system sales in the US were \$86.2 million (\$65.1 million end-user metallic stents) for the first quarter of 2004 compared to \$134.4 million (\$117.3 million end-user metallic stents) for the first quarter of 2003. In February 2004, Guidant entered into an agreement with Johnson & Johnson to co-promote Cordis' CYPHER™ Sirolimus-eluting Coronary Stent. This agreement also allows for co-promotion of future drug eluting stents sold by Johnson & Johnson. Co-promotion commissions Guidant earns under this agreement, along with sales of stent delivery systems (dilatation catheters) to Johnson & Johnson are included in US coronary stent system sales. US end-user metallic coronary stent system sales (which exclude revenues associated with Johnson & Johnson) now account for 7% of Guidant's worldwide revenues compared to 14% in the first quarter of 2003. These revenues are expected to continue to decline as US drug eluting stent penetration continues. International sales of coronary stent systems in the first quarter of 2004 were \$85.2 million compared to \$86.6 million in the first quarter of 2003. Competitive launches of metallic and drug eluting stents in Japan during 2004 are expected to impact future international sales of these systems. Coronary stent system sales in 2004 primarily include:

- o MULTI-LINK™ VISION™ Coronary Stent System

- o MULTI-LINK ZETA™ Coronary Stent System
- o MULTI-LINK PENTA™ Coronary Stent System
- o MULTI-LINK PIXEL™ Coronary Stent System, designed to treat small-diameter vessels in patients presenting with abrupt or threatened abrupt closure

In April 2004, Guidant announced CE Mark approval of the MULTI-LINK FRONTIER™ Coronary Bifurcation Stent System, which is specifically designed to treat plaque in coronary arteries at the site of a bifurcation, where one vessel branches from another.

#### Angioplasty Systems

Angioplasty system sales totaled \$116.6 million in the first quarter of 2004 compared to \$99.6 million in the first quarter of 2003, reflecting 17% sales growth. Sales growth is primarily attributable to unit volume increases for guidewires, due to the increased number of metallic and drug eluting stents being implanted and more complex lesions being treated.

#### Cardiac Surgery, Biliary, Peripheral and Carotid Systems

Worldwide sales of cardiac surgery, biliary, peripheral and carotid systems totaled \$61.6 million in the first quarter of 2004, representing 34% growth over the same period in 2003. Sales growth was driven by:

- o VASOVUE® Endoscopic Vessel Harvesting System
- o .035 Platforms: ABSOLUTE™ Self Expanding Stent, OMNILINK® Balloon Expandable Stent and AGILTRAC™ Peripheral Dilatation Catheter
- o RX ACCULINK™ Carotid Stent System in Europe including the RX ACCUNET™ Embolic Protection System

#### **Cost of Products Sold**

Cost of products sold was \$226.3 million in the first quarter of 2004 compared to \$205.1 million for the same period in 2003. Gross profit percentage was 75.8% for the first quarter of 2004 compared to 76.1% for the first quarter of 2003. The change in gross profit percentage was driven by the decrease in stent sales, partially offset by continued sales mix shift toward higher value implantable defibrillator systems, including CRT-D systems, and increased manufacturing efficiencies.

#### **Research and Development**

Guidant continued its commitment to product innovation by increasing its investment in research and development in the first quarter of 2004. Research and development expense was \$137.6 million for the first quarter of 2004, or 14.7% of sales, compared to \$112.8 million in the first quarter of 2003, or 13.2% of sales. Significant investments in research and development in the first quarter of 2004 included:

- o Guidant's two primary drug eluting stent programs:
  - The first program is the CHAMPION™ Everolimus Eluting Stent System mounted on the VISION stent delivery system. It has a bioabsorbable polymer matrix and is being evaluated in the FUTURE family of clinical trials.
  - The second program is the MULTI-LINK VISION Everolimus Eluting Stent System, which is currently being evaluated in the SPIRIT FIRST Clinical Trial and includes a durable polymer matrix.
- o Bioabsorbable stent research and development
- o Advanced Patient Management™ applications, designed to enable physicians to monitor patient heart function

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remotely and automatically

- o Clinical trials to further demonstrate the benefits of cardiac resynchronization therapy devices for treating heart failure
- o Development of next-generation devices for cardiac rhythm management, carotid stent systems and cardiac surgery products

*Important research and development milestones in 2004 included:*

- o FUTURE III Clinical Trial – Study designed to provide additional safety and performance data on the CHAMPION Everolimus Eluting Stent System. Enrollment in this clinical trial began in April 2004 and is expected to include 800 patients.
- o SPIRIT FIRST Clinical Trial – Feasibility study for durable polymer drug eluting stent to support filings for larger US and European pivotal trials. Enrollment of 60 patients was completed in April 2004.
- o DECREASE HF Clinical Trial – Heart failure study designed to demonstrate the safety and effectiveness of the flexible pacing modes offered in Guidant's newest CRT-D systems. Enrollment of 360 patients was completed in April 2004.
- o CONTAK RENEWAL 3 AVT Clinical Trial – Study designed to study the effect of device therapy in patients who suffer from both heart failure and atrial arrhythmias. Guidant expects to complete enrollment in the third quarter of 2004.
- o Acculink for Revascularization of Carotids in High Risk Patients (ARCHeR) Clinical Trial – Study designed to evaluate the safety and effectiveness of carotid artery stenting as a minimally invasive alternative for treating carotid artery disease in patients ineligible for surgery or at high surgical risk. The Company announced positive one-year results in March 2004. Guidant also announced positive 30-day results from its third clinical trial designed to evaluate carotid stenting, the ARCHeR 3 Clinical Trial in March 2004.

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#### **In-Process Research and Development (IPRD)**

Guidant recorded a \$26.8 million pre-tax IPRD charge in the first quarter of 2004. This charge includes \$22.8 million associated with the acquisition of AFx, inc., a manufacturer of microwave surgical cardiac ablation medical devices, for the technology that had not reached technological feasibility and had no alternative use. See Note 9 to the consolidated financial statements for further details regarding this acquisition. The remaining charge was primarily for the purchase of technology to be utilized in conjunction with Guidant's carotid stent systems.

Guidant recorded a pre-tax IPRD charge of \$36.5 million in the first quarter of 2003 related to the following acquisitions:

- o Biosensors International – Guidant purchased certain assets of Biosensors International (Biosensors), resulting in \$20.5 million of IPRD. Guidant also obtained an exclusive worldwide license to Biosensors' polymer formulation technology in the field of everolimus eluting stents and a non-exclusive license to this technology for use with other drugs in drug eluting stents. Additionally, Guidant acquired the option of manufacturing and commercializing the Biosensors everolimus eluting stent that has been used in Biosensors' FUTURE I and II clinical trials.
- o Bioabsorbable Vascular Solutions – Guidant purchased the majority interest in Bioabsorbable Vascular Solutions (BVS), an early-stage developer of bioabsorbable stents, resulting in a \$16.0 million IPRD charge. In April 2004, an additional IPRD charge was recorded when the remaining interest was purchased for \$6.0 million. Bioabsorbable stents are designed to be fully absorbed by tissue following the restoration of blood flow in patients with coronary artery disease.

#### **Sales, Marketing and Administrative**

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Sales, marketing and administrative expenses were \$314.7 million for the three months ended March 31, 2004, compared to \$269.0 million for the same period in 2003, an increase of 17%. The increases were driven primarily by compensation associated with sales growth and the increase in the cardiac rhythm management sales force.

Total expenses in the first quarter of 2004 included \$14.7 million of compensation expense as a result of restricted stock grants made under the 2003 performance-based equity compensation program, including accelerated vesting due to the final share price appreciation target of 75% growth achieved from the grant date (February 2003) through January 2004. This represents an increase in restricted stock expense of \$11.9 million compared to the first quarter of 2003. These expenses were classified in the income statement consistent with the functional area of related employees.

#### **Interest**

Net interest income was \$1.0 million for the three months ended March 31, 2004, compared to \$1.4 million for the same period in 2003. The decrease in net interest income from 2003 was driven by a higher average outstanding debt balance, which was partially mitigated by increased interest income from larger balances in cash and cash equivalents and short-term investments. Guidant currently manages interest rate risk by using interest rate swap agreements to convert fixed-rate debt to variable-rate debt.

#### **Royalties**

Net royalties expense totaled \$12.1 million in the first quarter of 2004 compared to \$13.3 million for the same period in 2003. Net royalty expense included royalty income of less than \$1.0 million in all periods presented. Royalty expense is incurred for sales of certain implantable defibrillator systems, pacemaker systems and stent delivery systems. The decrease was primarily due to the December 2003 expiration of the Mirowski patent covering certain implantable defibrillator products. At the end of the first quarter, the Company has accrued royalties and interest of \$58.1 million under a license agreement pertaining to that patent, the ultimate payment of which will depend on the Federal Circuit Court of Appeals ruling on a competitor's challenge to the patent's validity, claim construction and term extension. (See Part II, Item 1, Legal Proceedings.)

#### **Income Tax**

The effective income tax rates for the quarters ended March 31, 2004 and 2003 were 26.4% and 27.0%. Guidant's ongoing operations are impacted by overseas operations having statutory tax rates that are lower than the US statutory tax rates.

#### **Discontinued Operations**

In March 2004, Guidant's Board of Directors approved a plan to discontinue the GALILEO® Intravascular Radiotherapy System (GALILEO System) product line for the treatment of in-stent restenosis due to the significant competitive impact of drug eluting stents. On April 21, 2004, Guidant signed a definitive agreement with Novoste Corporation (Novoste) to cooperate in assisting existing US and Canadian customers of the GALILEO System who wish to transition to Novoste products. Guidant received \$2.5 million upon signing and will receive earn-out payments up to a maximum of \$4.0 million based on Novoste sales in the US and Canada. The disposal plan consists primarily of the termination of normal activity, abandonment of property and equipment, product returns, collection of accounts receivable and settlement of liabilities. Net loss from discontinued operations includes a charge of \$11.2 million during the quarter ended March 31, 2004, primarily related to the write down of long-lived assets to fair value and recording inventory and accounts receivable at net realizable value. Guidant expects this discontinuation to occur in several phases, concluding within the next six to nine months. The Company expects to incur pre-tax losses of between \$22.0 million and \$28.0 million associated with the exit for the remainder of 2004. Following a brief transition period, Guidant will close its Houston and Pearland, Texas, facilities.

In June 2003, Guidant's Board of Directors approved a plan to dispose of the ANCURE ENDOGRAFT System product line to treat abdominal aortic aneurysms (AAA) due to continuing financial losses, limited prospects for the Company's AAA product line and the impact of the Department of Justice investigation.

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In December 2003, Guidant's Board of Directors ratified a plan to discontinue Guidant's operations in Brazil due to unfavorable business conditions and poor operating performance.

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In accordance with SFAS 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, these disposals represent discontinued operations. Accordingly, the accompanying consolidated financial statements and notes reflect the results of operations and financial position of the AAA and GALILEO product lines and the Brazil operations as discontinued operations for all periods presented. Net loss from discontinued operations includes charges related to the impairment of certain long-lived assets, inventory write-downs, customer returns and accruals for employee severance and lease commitments. Net loss from discontinued operations in 2003 also includes charges related to litigation settlements.

The following summarizes financial information for discontinued operations (in millions):

	Three Months Ended March 31,	
	2004	2003
Net sales	\$11.3	\$27.5
Loss from discontinued operations before income taxes	21.1	64.0
Net loss from discontinued operations	13.6	63.0

#### LIQUIDITY AND FINANCIAL CONDITION

	March 31, 2004	December 31, 2003
<i>(Dollars in millions)</i>		
Cash and cash equivalents (1)	\$ 1,612.3	\$ 1,468.2
Working capital	\$ 2,329.6	\$ 2,017.5
Current ratio	3.6:1.0	2.9:1.0
Net cash position (2)	\$ 587.2	\$ 519.9
Days receivable outstanding	79	78
Inventory turnover	2.22	2.38

(1) A substantial portion of cash and cash equivalents is indefinitely invested in Guidant's non-US subsidiaries.

(2) Net cash position is the sum of cash and cash equivalents less total debt.

Certain of Guidant's acquisitions involve contingent consideration. Payment of the additional consideration is generally contingent upon reaching performance-related milestones, including specified revenue levels, product development targets or regulatory approvals or filings. At March 31, 2004, Guidant's accrual for milestone obligations totaled \$8.3 million to be paid during the next three years. In addition, future undiscounted contingent consideration for performance-related milestones on acquisitions of up to \$465.0 million could be paid through 2010, depending on when and if milestones are attained. Potential milestone payments under existing agreements during the next 12 months range from \$6.0 to \$118.0 million. The Company continues to evaluate business development opportunities, which may generate additional payments.

#### Summary of Cash Flows

	Three Months Ended March 31,		
	2004	2003	Change
<i>(In millions)</i>			
Net cash provided by (used for):			
Operating activities	\$ 131.2	\$ 110.3	\$ 20.9
Investing activities	(113.8)	(53.3)	(60.5)
Financing activities	134.7	9.5	125.2
Effect of exchange rate changes on cash	(8.0)	23.7	(31.7)
Net increase in cash and cash equivalents	\$ 144.1	\$ 90.2	\$ 53.9

Net cash provided by operating activities was \$131.2 million for the first three months of 2004, an increase of \$20.9 million

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from the same period in 2003 primarily due to an increase of \$128.2 million increase in net income, adjusted for non-cash items, partially offset by a decrease in taxes payable.

Net cash used for investing activities was \$113.8 million for the first three months of 2004, an increase of \$60.5 million from the prior year primarily due to the following:

- o \$48.4 million for the acquisition of AFx, inc.
- o \$24.4 million increase in net additions of property and equipment, primarily for buildings due to the growth of the cardiac rhythm management product lines

Net cash provided by financing activities was \$134.7 million for the first quarter of 2004, an increase of \$125.2 million from the prior year due to the following:

- o \$177.8 million increase in issuances of common stock for stock option exercises
- o \$75.6 million increase in borrowings

partially offset by:

- o \$97.2 million repurchase of common stock
- o \$31.0 million in dividend payments

Exchange rate fluctuations decreased cash by \$8.0 million for the three months ended March 31, 2004 compared to an increase in cash of \$23.7 million for the three months ended March 31, 2003. This decrease of \$31.7 million is primarily due to the Euro weakening during the quarter ended March 31, 2004 and strengthening during the quarter ended March 31, 2003 compared to the US dollar.

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At March 31, 2004, the Company had outstanding borrowings of \$1,025.1 million at a weighted average interest rate of 1.76%, including bank borrowings, commercial paper, \$350.0 million principal balance in long-term notes due in 2006 and interest rate swap agreements valued at \$7.2 million. Bank borrowings represent short-term uncommitted credit facilities with commercial banks. The commercial paper borrowings are supported by two credit facilities aggregating \$800.0 million. There are currently no outstanding borrowings under these facilities. The Company classified \$250.0 million as short-term debt at March 31, 2004. The Company believes that cash and cash equivalent balances will be adequate to fund maturities of short-term borrowings, obligations to make interest payments on its debt and other anticipated operating cash needs for 2004, including planned capital expenditures of approximately \$125.0 million for the remainder of 2004.

The Company has recognized net deferred tax assets aggregating \$283.6 million at March 31, 2004, compared to \$314.1 million at December 31, 2003. In view of the consistent profitability of its past operations, the Company believes that these assets will be substantially recovered and that no significant additional valuation allowances are necessary.

#### Significant Accounting Policies

It is important to understand Guidant's accounting policies in order to understand its financial statements. The most significant policies are described in Note 2 and elsewhere in the Notes to the Consolidated Financial Statements in the Company's latest Annual Report on Form 10-K.

In preparing the financial statements in accordance with generally accepted accounting principles, management must often make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and related disclosures at the date of the financial statements and during the reporting period. Some of those judgments can be subjective and complex. Consequently, actual results could differ from those estimates. The accounting policies that are most subject to important estimates or assumptions include those described below. The Notes to the Consolidated Financial Statements in our latest Annual Report on Form 10-K described above and this 10-Q provide additional information about management's evaluation of these items.

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Guidant continually evaluates the accounting policies and estimates it uses to prepare the consolidated financial statements. In cases where management estimates are used, they are based on historical experience, information from third-party professionals, and various other assumptions believed to be reasonable.

Inventory Reserves — The Company values its inventory at the lower of cost (first-in, first-out method) or market. Reserves are estimated for excess, slow moving and obsolete inventory as well as inventory with a carrying value in excess of its net realizable value. Write-offs are recorded when product is destroyed. The Company reviews inventory on hand at least quarterly and records provisions for excess and obsolete inventory based on several factors, including current assessment of future product demand, anticipated release of new products into the market, historical experience and product expiration. The Company's industry is characterized by rapid product development and frequent new product introductions. Uncertain timing of product approvals, variability in product launch strategies, product recalls and variation in product utilization all impact the estimates related to excess and obsolete inventory.

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Product Warranties — Provisions for estimated expenses related to product warranties are recorded at the time the products are sold. Estimates for warranty costs are calculated based primarily upon historical warranty experience, but may include assumptions related to anticipated changes in warranty costs and failure rates. Assumptions and historical warranty experience are evaluated on at least a quarterly basis to determine the continued appropriateness of such assumptions. Warranty cost accruals are adjusted from time to time when warranty claim experience differs from estimates.

Valuation of Purchased In-Process Research and Development (IPRD), Goodwill and Other Intangible Assets — When a business combination occurs, the purchase price is allocated based upon the fair value of tangible assets, intangible assets, IPRD and goodwill. The Company recognizes IPRD in business combinations for the portion of the purchase price allocated to the appraised value of in-process technologies, defined as those technologies relating to products that have not received FDA approval and have no alternative future use. The portion assigned to in-process technologies excludes the value of core and developed technologies, which are recognized as intangible assets when purchased. Valuations require the use of significant estimates. The amount of the purchase price allocated to IPRD is determined by estimating future cash flows of the technology and discounting net cash flows back to present values. The Company considers, among other things, the projects' stage of completion, complexity of the work completed as of the acquisition date, costs already incurred, projected costs to complete, contribution of core technologies and other acquired assets, expected introduction date and the estimated useful life of the technology. The discount rate used to arrive at a present value as of the date of acquisition is based on the time value of money and medical technology investment risk. Goodwill represents the excess of cost over fair value of identifiable net assets of the business acquired and the amount allocated to IPRD. The methodologies used in arriving at these estimates are in accordance with accepted valuation methods.

Income Taxes — All income tax amounts reflect the use of the liability method. Under this method, deferred tax assets and liabilities are determined based on the expected future tax consequences of temporary differences between the carrying amounts of assets and liabilities for financial and income tax reporting purposes.

Guidant operates in multiple tax jurisdictions with different tax rates and must determine the allocation of income to each of these jurisdictions based on estimates and assumptions. In the normal course of business, the Company will undergo scheduled reviews by taxing authorities regarding the amount of taxes due. These reviews include questions regarding the timing and amount of deductions and the allocation of income among various tax jurisdictions. Tax reviews often require an extended period of time to resolve and may result in income tax adjustments if changes to the allocation are required between jurisdictions with different tax rates.

Legal Proceedings and Other Loss Contingencies — The Company is subject to various legal proceedings, many involving routine litigation incidental to the business. Other matters contain allegations that are not routine and involve compensatory, punitive or treble damage claims, or claims for injunctive relief related to alleged infringement of a third party's patents, or seek declarations affecting the validity of the Company's patents. Litigation outcomes are not within the Company's complete control, are often very difficult to predict and often are resolved over long periods of time. Estimating probable losses requires the analysis of multiple possible outcomes that often depend on judgments about potential actions by third parties. Contingencies are recorded in the consolidated financial statements, or otherwise disclosed, in accordance with SFAS 5, *Accounting for Contingencies*.

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## Field Actions

As further described in the Company's Annual Report on Form 10-K and Exhibit 99 to this filing, the medical device industry is subject to substantial regulation, including by the FDA and comparable international agencies. In addition to requiring clearance or approval to market new or improved devices, the Company is subject to regulation as a device manufacturer. Regulations cover many aspects of the Company's operations, including quality systems, marketing and device reporting.

From time to time, the Company initiates field actions with respect to market-released products. These actions may include product recalls or communications with a significant number of physicians about a product or labeling issue. The scope of such actions can range from very minor issues affecting a small number of units to more significant actions. Since the Company's last filing on Form 10-K, the Company conducted the following field actions:

In March 2004, certain lots of size 8 French guide catheters, used to assist in placement of Guidant's heart failure lead delivery system, were recalled due to a component issue. Regulatory authorities were notified and the component issue has been resolved.

In April 2004, Guidant issued a field notification to physicians related to the HEARTSTRING™ Proximal Seal. The communication described specific steps the physician should use for the deployment and removal of the device. FDA was notified and no product was required to be returned. Regulatory authorities outside the US were also notified.

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## Cautionary Factors

Certain statements made in this report are forward-looking, including accounting estimates, statements concerning sales trends, anticipated tax rates, capital expenditures, cash flows, costs of research programs, the timing of discontinued operations and the timing of product developments. The statements are based on assumptions about many important factors, including assumptions concerning:

- o The development of the coronary stent market: Drug eluting stents present a significant growth opportunity; however, the earlier introduction of drug eluting stents by the Company's competitors has substantially affected the market for metallic coronary stents and will continue to impact the Company's financial results.
- o The effects of operating in a highly regulated industry, the necessity for appropriate reimbursement of therapies and the significance of legal claims in Guidant's industry.
- o Changes in the location or volume of production or changes in tax law.
- o Product development and production factors (including the uncertainties associated with clinical trials), competitive factors (including the introduction of new products and alternative therapies), business development factors, internal factors (including the retention of key employees and changes in business strategies) and others, all as further described in Exhibit 99 to this filing, which is incorporated herein by reference.

Actual results may differ materially. The Company does not undertake to update its forward-looking statements.

## Item 4. Controls and Procedures

An evaluation was carried out, under the supervision of and with the participation of the Company's management, including the Company's chief executive officer (CEO) and chief financial officer (CFO), of the effectiveness of the Company's disclosure controls and procedures as of the end of the period covered by this report. Based on the evaluation, the CEO and CFO have concluded that the Company's disclosure controls and procedures are effective.

There was no change in the Company's internal control over financial reporting during the Company's most recently completed fiscal quarter that has materially affected, or is reasonably likely to materially affect the Company's internal control over financial reporting.

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Section 404 of the Sarbanes-Oxley Act requires company management to assess and report on the company's internal controls. It also requires a company's independent, outside auditors to issue an "attestation" to management's assessment, as well as assess the proper design and function of internal controls. Guidant expects to be required to comply with this requirement for the first time as of December 31, 2004. Guidant has substantially completed the documentation to comply with this standard and is now working on management testing of internal controls.

## PART II OTHER INFORMATION

### Item 1. Legal Proceedings

The Company is involved in patent, product liability, shareholder and other legal proceedings that arise in the course of the Company's business. The Company records a liability when a loss is considered probable and the amount can be reasonably estimated. If the reasonable estimate of a probable loss is a range, and no amount within the range is a better estimate, the lower end of the range is accrued. If a loss is not probable or a probable loss cannot be reasonably estimated, no liability is recorded.

Patent and other proprietary rights are essential to the Company's business. Significant litigation concerning patents and products is pervasive in the Company's industry. Patent claims include challenges to the coverage and validity of the Company's patents on products or processes as well as allegations that the Company's products infringe patents held by competitors or other third parties. Although the Company believes that it has valid defenses to these challenges with respect to material patents, there can be no assurance as to the outcome of these matters, and a loss in any of these cases could result in a loss of patent protection or the ability to market products, which could lead to a significant loss of sales, or otherwise materially affect future results of operations.

Losses in the matters below are not considered probable or cannot be reasonably estimated. Accordingly, the Company has not recorded reserves for these matters. While the liability of the Company in connection with the claims cannot be estimated with any certainty, the outcome of these legal proceedings, except as specifically identified below, is not expected to have a material adverse effect on the Company's consolidated financial position, although the resolution in any reporting period of one or more of these matters could have a significant impact on the Company's results of operations for that period. While the Company believes that it has valid defenses in these matters, litigation is inherently uncertain, excessive verdicts do occur, and the Company may in the future incur material judgments or enter into material settlements of claims.

On February 18, 1998, Arterial Vascular Engineering, Inc. (now known as Medtronic Vascular) filed suit against the Company's subsidiary, Advanced Cardiovascular Systems, Inc. (ACS), in the District Court for Delaware alleging that the sale of MULTI-LINK family of coronary stent systems infringes the Boneau patents owned by Medtronic Vascular. The suit is consolidated with a suit by ACS alleging infringement by Medtronic Vascular of the Company's Lau stent patents. The Medtronic Vascular complaint also alleges misappropriation of trade secrets and breach of a confidentiality agreement by ACS. In the lawsuit, Medtronic Vascular is seeking injunctive relief, co-ownership of the Lau patents, monetary damages and a ruling that the ACS stent patents asserted against Medtronic Vascular are invalid. Pretrial matters are scheduled through 2004, with trial set in the first quarter of 2005. This suit is one of a number of suits brought by Medtronic Vascular under the Boneau patents against all substantial participants in the stent market. The allegations made by Medtronic Vascular are wide-ranging and cover the Company's products broadly. Accordingly, while potential liability cannot be estimated with any certainty, an adverse outcome could have a material impact on results of operations or consolidated financial position.

On June 15, 2000, Medtronic, Inc. (Medtronic) filed a declaratory judgment action against the Company and its Cardiac Pacemakers, Inc. (CPI) subsidiary in the District Court for Minnesota requesting that the court rule that Medtronic does not infringe certain of CPI's patents for atrial fibrillation technology or that the patents are not valid. Subsequently, the Company asserted additional patents related to atrial fibrillation technology against Medtronic in the same court. Currently, eight patents are being asserted against Medtronic in this consolidated litigation. Pretrial matters are scheduled into the second half of 2004.

On March 6, 2002, Pacesetter, Inc. (Pacesetter), a subsidiary of St. Jude Medical, Inc. (St. Jude), filed suit against the Company's subsidiaries, CPI and Guidant Sales Corporation (GSC), in the Central District of California alleging that CPI



and GSC have infringed a number of Pacesetter patents covering various features of pacemakers and implantable defibrillators. On the Company's motion, the case was transferred to the District Court for Minnesota. Pacesetter is seeking injunctive relief, monetary damages and attorney fees. Currently four patents are at issue. Pacesetter has sought reexamination of two of the patents. On the Company's motion, the litigation has been stayed pending the completion of the reexaminations.

On April 14, 2003, Medinol Ltd. filed suit against the Company and its ACS subsidiary in the Southern District of New York alleging that the sale of the Company's MULTI-LINK ZETA and MULTI-LINK PENTA Coronary Stent Systems infringe five Medinol patents related to stent design. The complaint seeks injunctive relief and monetary damages. Pretrial matters are scheduled through most of 2004.

On June 12, 2003, the Company announced that its subsidiary, EndoVascular Technologies, Inc. (EVT), had entered into a plea agreement with the US Department of Justice relating to a previously disclosed investigation regarding the ANCURE ENDOGRAFT System for the treatment of abdominal aortic aneurysms. At the time of the EVT plea, the Company had outstanding fourteen suits alleging product liability related causes of action relating to the ANCURE System. The Company settled eleven of the suits that predated the EVT plea for an amount recorded in the third quarter of 2003 that was not material to the Company. Subsequent to the EVT plea, the Company has been served with approximately thirty-five additional individual complaints, and more such suits are likely to be filed. A consolidated class action complaint covering ANCURE recipients is also pending in the Northern District of California. These cases generally allege that plaintiffs died or suffered other injuries as a result of purported defects in the device or the accompanying warnings and labeling. The complaints seek damages, including punitive damages, and equitable relief. An additional complaint includes state-law allegations of unfair trade and business practices relating to sales of the product. While the Company maintains insurance that may serve to reduce the Company's exposure with respect to these claims, one of the Company's carriers, Allianz Insurance Company (Allianz), has filed suit in the Circuit Court, State of Illinois, County of DuPage, seeking to rescind or otherwise deny coverage, and additional carriers have sought to intervene in the case. The Company also has initiated suit against certain of its carriers, including Allianz, in the Superior Court, State of Indiana, County of Marion, in order to preserve the Company's rights to coverage.

Also following the EVT plea, the Company has been served with securities class action and shareholder derivative complaints relating to the ANCURE System. A consolidated securities class action, which names as defendants the Company, EVT and certain of their current and former officers, is pending in the Southern District of Indiana. Generally, it is alleged that during all or a portion of the period from June 23, 1999, through June 12, 2003, public statements by the Company relating to the ANCURE System were false and misleading. Damages are sought on behalf of persons who purchased or otherwise acquired Company shares during that period. The Company has filed a motion to dismiss the case, which motion is fully briefed.

The derivative suits relating to the ANCURE System currently are pending in the Southern District of Indiana and in the Superior Court of the State of Indiana, County of Marion. The suits, purportedly filed on behalf of the Company, generally allege that the Company's directors breached their fiduciary duties by taking improper steps or failing to take steps to prevent the ANCURE and EVT related matters described above. The complaints seek damages and other equitable relief. The state court suits have been stayed in favor of the federal action. The Company has filed a motion to dismiss the federal action, which motion is fully briefed.

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On August 29, 2003, Medtronic filed a declaratory judgment action in the District Court for Delaware against the Company, GSC, Eli Lilly and Company (Lilly), and Mirowski Family Ventures L.L.C. (Mirowski), challenging its obligation to pay royalties to Mirowski on certain devices by alleging the invalidity of certain claims of US patent RE 38,119 ('119), which patent relates to cardiac resynchronization therapy and bi-ventricular pacing therapy. The '119 patent is exclusively licensed to the Company as part of a broader license covering Mirowski patents and is sublicensed to Medtronic. The parties have agreed to an expedited proceeding with limited scope and a bench trial is scheduled in August 2004.

On February 2, 2004, the Company, GSC, CPI and Mirowski filed a declaratory judgment action in the District Court for Delaware against St. Jude and Pacesetter alleging that their Epic HF, Atlas HF, and Frontier 3x2 devices will infringe the '119 patent (described in the prior paragraph) when those devices are approved for sale in the US.

On February 24, 2004, the Company's subsidiary, CPI, filed a patent infringement action in the District Court of Minnesota against St. Jude and Pacesetter alleging that their Quicksite over-the-wire pacing lead has infringed US Patent No. 5,755,766/Reexamination Certificate No. 5,755,766 C1 ("the '766 Patent").



On February 24, 2004, the Company entered into an agreement with Johnson & Johnson (J&J) to co-promote the CYPHER Sirolimus-eluting Coronary Stent in the US. Previously, Boston Scientific Corporation (BSC) sued J&J in the U.S. District Court for the District of Delaware alleging that the CYPHER stent infringes certain patents owned by BSC. On March 16, 2004, BSC filed an amended complaint adding the Company as a defendant. Under the terms of the agreement with J&J, J&J is required to indemnify the Company.

Anna Mirowski, Lilly and two Company subsidiaries, GSC and CPI, are plaintiffs in a patent infringement suit originally filed against St. Jude and its affiliates in November 1996 in the District Court in Indianapolis. The suit alleges that St. Jude's defibrillator products infringe patents licensed to CPI. In July 2001, a jury found that two of the licensed patents were valid and that St. Jude had infringed one, a patent that expired in March 2001. The jury awarded damages of \$140.0 million against St. Jude. The Company did not record a gain given the uncertainty remaining as to the ultimate resolution. On February 13, 2002, the court, in ruling on a number of post-trial motions, reversed each of the three jury findings above, along with the jury award. The court awarded St. Jude certain post-trial fees and costs (in an immaterial amount), along with contingent expenses and attorney fees upon any retrial of the case if a retrial is required following any appeal of the court's rulings. Cross appeals are pending in the Federal Circuit Court of Appeals.

## Item 2. Changes in Securities, Use of Proceeds and Issuer Purchases of Equity Securities

The following table provides information about purchases by the Company during the quarter ended March 31, 2004, of the Company's common shares:

<u>Period</u>	<u>Total Number of Shares Purchased (1)</u>	<u>Average Price Per Share</u>	<u>Total Number of Shares Purchased as Part of Publicly Announced Program</u>	<u>Approximate Dollar Value of Shares That May Yet Be Purchased Under the Program</u>
01/01/04- 01/31/04	--	--	--	--
02/01/04- 02/29/04	--	--	--	\$250.0 million
03/01/04- 03/31/04	1.2 million	\$69.11	1.2 million	\$167.0 million

- (1) Guidant repurchased an aggregate of 1.2 million common shares pursuant to the repurchase program publicly announced on February 17, 2004.

## Item 6. Exhibits and Reports on Form 8-K.

- (a) Exhibits. The Exhibit Index is incorporated herein by reference.
- (b) Reports on Form 8-K. During the quarter for which this Report on Form 10-Q is filed, the Registrant filed one current report on Form 8-K dated January 29, 2004, describing pursuant to Item 12 the Company's earnings release of the same date.

## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

GUIDANT CORPORATION  
(Registrant)

2/9/2007

Date: May 7, 2004

/s/ Keith E. Brauer  
Vice President, Finance and  
Chief Financial Officer

Date: May 7, 2004

/s/ Peter J. Mariani  
Vice President, Corporate  
Controller and Chief  
Accounting Officer

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#### EXHIBIT INDEX

- Exhibit 10.28: Amendments through and including Settlement and Release Agreement and Amendment to Master License Agreement dated February 24, 2004 by and between the Company, Johnson & Johnson and their respective affiliates, portions of which have been omitted pursuant to a request for confidential treatment.
- Exhibit 31.1: Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of Ronald W. Dollens
- Exhibit 31.2: Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of Keith E. Brauer
- Exhibit 32.1: Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of Ronald W. Dollens
- Exhibit 32.2: Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of Keith E. Brauer
- Exhibit 99: Factors Possibly Affecting Future Operating Results

2/9/2007

EX-10 2 ex10\_28.htm

EXHIBIT 10.28  
EXECUTION COPY**SETTLEMENT AND RELEASE AGREEMENT**

and

**AMENDMENT TO MASTER LICENSE AGREEMENT**

This Settlement and Release Agreement and Amendment to Master License Agreement (this "Agreement"), made as of this 24<sup>th</sup> day of February, 2004, by and among Advanced Cardiovascular Systems, Inc., a California corporation having a principal place of business at 3200 Lakeside Drive, Santa Clara, California 95052-8167 ("ACS"), Guidant Corporation, an Indiana corporation having a place of business at 111 Monument Circle, 20th Fl., Indianapolis, IN 46204 ("Guidant Corporation"), and collectively, with ACS and its other Affiliates, "GUIDANT", Cordis Corporation, a Florida corporation having a principal place of business at 14201 NW 60th Avenue, Miami, Florida 37014 ("CORDIS"), and Johnson & Johnson, a New Jersey corporation having a place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933 ("Johnson & Johnson"), and collectively, with CORDIS and its other Affiliates, "J&J". For purposes of this Agreement, capitalized terms used but not otherwise defined herein shall have the meanings ascribed to such terms in the Master License (as defined below).

RECITALS

CORDIS, ACS and GUIDANT CORPORATION have entered into a Master License Agreement, dated as of April 3, 2000 and further amended on December 3, 2001 and November 24, 2003 (the "Master License"), pursuant to which, among other things, the parties have provided each other access to certain of their respective technologies, including, without limitation, (i) GUIDANT's licensing of certain rights to the Lam/Lau Patents to CORDIS and (ii) CORDIS's licensing of certain rights to Stent Implant Patents to GUIDANT;

In connection with entering into the Master License, CORDIS, ACS and GUIDANT CORPORATION entered into an Arbitration Agreement, dated as of April 3, 2000 (the "Arbitration Agreement"), pursuant to which the parties provided for the resolution of multiple patent litigations with one another along with the resolution of future disputes;

Pursuant to the terms of the Master License and the Arbitration Agreement, GUIDANT has commenced an arbitration (the "Lam/Lau Arbitration") against CORDIS alleging that certain CORDIS products infringe upon certain Lam/Lau Patents and that CORDIS is obligated to pay royalties to GUIDANT in connection with its licensing of the Lam/Lau Patents (the "Lam/Lau Dispute");

J&J has alleged that certain GUIDANT products infringe upon U.S. Patent [\*\*\*]/() to Fischell et. al. and assigned to CORDIS (the "Fischell Dispute");

The parties have decided that it is in their respective best interests to conclude a full and final settlement of all claims asserted, or that could have been asserted, against one another arising out of the Lam/Lau Dispute and the Fischell Dispute in accordance with the terms, conditions and limitations set forth herein; and

In connection with (and as additional consideration for) entering into this Agreement, the parties are simultaneously entering into separate agreements that (i) grant ACS the right to act as a sales agent for CORDIS's drug eluting stent products, (ii) grant CORDIS the right to act as a sales agent for ACS's coronary bioabsorbable vascular stent products if ACS commences commercial sales of such products, (iii) grant CORDIS the right to purchase from ACS certain ACS coronary stent delivery system products for use in CORDIS's drug eluting stent products, and (iv) provide for the cross licensing of certain intellectual property rights in the drug eluting stent field.

NOW, THEREFORE, in consideration of the mutual covenants expressed herein, the agreements set forth in the preceding paragraph and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties, intending to be legally bound, hereby agree as follows:

2/9/2007

1. The parties acknowledge that this Agreement is being executed in settlement and compromise of the Lam/Lau Dispute and the Fischell Dispute and that nothing in this Agreement shall be construed as an admission by any party of any wrongdoing, or of the validity or invalidity of any position taken or proposed to be taken by or against the party in any past, present, or future dispute or proceeding.
2. The parties agree that the Master License shall be, and hereby is, amended as follows:

*(1) [\*\*\*] - Material has been omitted pursuant to a request for confidentiality.*

2/9/2007

- (a) The second sentence of subsection I of Section 1.12 is amended and restated in its entirety to be and read as follows: "Stent Implant Patents shall not include the Palmaz/Schatz Patents, the Lam/Lau Patents, the Lazarus Patents or the Fischell Patents."
- (b) A new subsection L is added to Section 1.12 as follows: "L. "Fischell Patents" shall mean those Patents directed to any device, at least a portion of which is placed within a blood vessel of the body to help maintain the patency of such blood vessels, owned, acquired or licensed by J&J in which Robert E. Fischell, Tim A. Fischell and/or David R. Fischell are a named inventor, including, without limitation, those included on Schedule 1L to this Agreement, and all and any continuations, continuations-in-part, divisionals, including any patents maturing therefrom and any patents of addition, reissues, re-examinations, renewals or extensions thereof, further including any Foreign Counterparts of such Patents, consistent with the definition of Patents in Section 1.12."
- (c) Section 2.2 is amended and restated in its entirety to be and read as follows: "GUIDANT hereby grants to CORDIS an irrevocable, non-exclusive, worldwide right and license (without the right to sublicense) to make, have made, use or sell, or otherwise dispose of Licensed Products under the Lam/Lau Patents in all fields, and to practice processes and methods under the Lam/Lau Patents in all fields. The license granted pursuant to this paragraph 2.2 shall be a paid-up license and any pass-through royalties payable in respect of past and future Net Sales by CORDIS of Licensed Products (including Net Sales of the relevant products that occurred prior to the Effective Date) shall be payable by GUIDANT."
- (d) A new Section 2.9A is added as follows: "2.9A Fischell Patents. CORDIS hereby grants to GUIDANT an irrevocable, non-exclusive, worldwide right and license (without the right to sublicense) to make, have made, use or sell, or otherwise dispose of Licensed Products under the Fischell Patents in all fields, and to practice processes and methods under the Fischell Patents in all fields. The license granted pursuant to this Section 2.9A shall be paid-up as to J&J. Any pass-through royalties payable with respect to Net Sales by GUIDANT of Licensed Products, including future Licensed Products (i) after the date of execution of this Agreement shall be payable by GUIDANT and (ii) prior to the date of execution of this Agreement shall be waived and, if payable, paid by CORDIS. (CORDIS represents that, unless noted on Schedule 1L, the pass-through royalty rate is [\*\*\*]). Payments under this Section 2.9A shall be made by GUIDANT to CORDIS, which shall then forward such payments as part of its contractual obligations."
- (e) The first sentence of Section 2.10 is amended and restated in its entirety to be and read as follows: "For purposes of Sections 2.4 above, if either CORDIS or GUIDANT believes that its patent is being infringed by any product of the other Party, other than a Current Product, such Party may give notice to the other Party."
- (f) The third sentence of Section 2.10 is amended and restated in its entirety to be and read as follows: "If the arbitrators determine that the disputed Patent is infringed, not invalid and enforceable, the arbitrators may designate an appropriate supplemental royalty rate [\*\*\*]."
- (g) The phrase "; provided, however, that any royalty rate in respect of the Lam/Lau Patents determined pursuant to paragraph 2.2 above shall be subject to an increase of up to [\*\*\*] over the Maximum Rate, pursuant to the provisions of paragraph 2.10 above" is hereby deleted from Section 2.12.
- (h) A new Schedule 1L is added as follows on Exhibit A to this Agreement.
3. Apart from the obligations created by, referenced, acknowledged or arising out of this Agreement and the other agreements being entered into pursuant to or in connection with this Agreement, J&J, on the one hand, and GUIDANT, on the other hand, do hereby for themselves and their respective legal successors and assigns, release and forever discharge each other and their respective shareholders, officers, directors, employees, agents, attorneys, customers, distributors, officials, legal successors and assigns of and from any and all claims, demands, damages, debts, liabilities, accounts, reckonings, obligations, costs, expenses, liens, actions and causes of action of any kind and nature whatsoever, whether now known or

unknown, suspected or unsuspected, which either now has, owns or holds or at any time heretofore had ever owned or held, based on or arising out of or relating to the Lam/Lau Dispute and the Fischell Dispute, all of which are referred to hereinafter as the "Released Matters", including, without limitation, (i) any and all disputes concerning the infringement, validity or enforceability of the Lam/Lau Patents or the Fischell Patents and (ii) any and all claims and counterclaims set forth in the arbitration proceedings commenced by GUIDANT in connection with the Lam/Lau Dispute. GUIDANT and J&J shall, as soon as practicable after the date hereof, take all steps necessary to terminate the Lam/Lau Arbitration. GUIDANT and J&J each shall pay its own costs, attorneys' fees and expenses, and equally divide any joint expenses, incurred in connection with the Released Matters. For the avoidance of doubt, the terms "J&J" and "GUIDANT," as used in this Agreement, shall include the Affiliates of such parties, and Guidant Corporation and Johnson & Johnson, respectively, shall ensure that its respective Affiliates so comply with this Agreement.

4. It is the intention of the parties hereto in executing this Agreement and in paying and receiving the consideration called for by this Agreement that this Agreement shall comprise a full and final accord and mutual release of all the Released Matters. Each of the parties acknowledges that it is aware that it or its attorneys or accountants may hereafter discover claims or facts in addition to or different from those which it now knows or believes to exist with respect to the Released Matters, but that it is its intention hereby to fully and finally and forever settle and release all Released Matters, whether known or unknown. The releases given herein shall remain as full and complete releases notwithstanding the discovery or existence of any such additional or different claim or fact.
5. Each of GUIDANT and J&J, by and on behalf of its predecessors, successors, heirs, executors, administrators, assigns, shareholders, officers, directors, attorneys, agents, employees and representatives, hereby waives with respect to the release of paragraphs 3 and 4 above the benefits of Section 1542 of the Civil Code of California to the extent that such benefits may contravene a provision hereof. Such section reads as follows: "1542. General Release Extent. A General Release does not extend to claims which the creditor does not know or suspect to exist in his favor at the time of executing the Release, which if known by him must have materially affected his settlement with the debtor."
6. GUIDANT and J&J hereby for themselves and their respective legal successors and assigns, hereby covenant not to bring any demand, claim or cause of action against one another and the other's respective shareholders, officers, directors, employees, agents, attorneys, customers, distributors, officials, legal successors and assigns of any kind or nature with respect to any and all claims, demands, damages, debts, liabilities, accounts, reckonings, obligations, costs, expenses, liens, actions and causes of action of any kind and nature whatsoever, whether now known or unknown, suspected or unsuspected which either now has, owns or holds or at any time heretofore had ever owned or held based on or arising out of or related to the Released Matters, including any allegation of infringement of the Lam/Lau Patents or the Fischell Patents, through the manufacture, use or sale of any allegedly infringing product that is or has been sold anywhere in the world as of or prior to the date hereof.
7. This Agreement is executed freely, voluntarily, in good faith, and without any duress or undue influence on any party, and with and upon the advice of counsel. Each of the undersigned represents and warrants that it has been given a full and fair opportunity to review this Agreement, and that it understands the terms, conditions, and obligations set forth herein. Each of the undersigned represents and warrants that it is a corporation duly organized, validly existing, and in good standing. Each of the undersigned represents and warrants that it has corporate power and authority to execute and deliver this Agreement and to perform its obligations hereunder, and all such action has been duly and validly authorized by all necessary corporate proceedings on its part. Each of the undersigned represents and warrants that this Agreement has been duly and validly executed and delivered and constitutes a legal, valid and binding obligation enforceable in accordance with the terms hereof, except as may be limited by bankruptcy, insolvency, or other similar laws of general application affecting the enforcement of creditors' rights or by general principles of equity limiting the availability of equitable remedies. Each of the undersigned represents and warrants that



neither the execution and delivery of this Agreement nor consummation of the transactions herein contemplated nor performance of or compliance with the terms and conditions hereof will (i) violate any material law, (ii) conflict with or result in a breach of or a default under the certificate of incorporation or bylaws of such party or any material agreement or instrument to which such party is a party or by which it or any of its properties may be subject or bound, or (iii) result in the creation or imposition of any lien upon any property of such party.

8. CORDIS represents and warrants that as of the date hereof it owns all right and title to or has the ability to grant the licenses to the Fischell Patents. As of the date hereof, CORDIS's right, title and interest in and to the Patents licensed by it pursuant to the amendment to the Master License included in paragraph 2(d) above is and during the term of the Master License shall continue to be free and clear of any lien, charge, security interest or encumbrance which would adversely affect or limit GUIDANT's exercise of its rights under the Master License.
9. The Master License, as further amended by this Agreement, is and shall continue to be in full force and effect and is hereby in all respects ratified and confirmed. Nothing in this Agreement shall waive or be deemed to waive or modify (except as expressly set forth herein) any rights or obligations of any of the parties under the Master License.
10. This Agreement, together with all other agreements referred to herein, shall constitute the entire agreement between the parties or their Affiliates with respect to the subject matter hereof, and shall supersede all previous negotiations, commitments and writings relating thereto (other than the Confidentiality Agreement dated [\*\*\*] between Guidant Corporation and Johnson & Johnson).
11. This Agreement shall not be modified or altered in any manner except by an instrument in writing executed by the parties hereto.
12. This Agreement shall inure to the benefit of, and be binding upon, Affiliates, agents, officers, directors, employees, shareholders, attorneys, assigns, representatives, and successors of the parties. There are no other third party beneficiaries of this Agreement.
13. This Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.
14. This Agreement shall be deemed to be executed and to be performed in the State of New York and shall be interpreted, governed and construed in accordance with the laws of the State of New York, without regard to its choice of law rules.
15. If any provision of this Agreement is found to be prohibited by law and invalid, or for any reason such provision is held unenforceable, in whole or in part, such provision shall be considered severable and its invalidity or unenforceability shall not affect the remainder of this Agreement, which shall continue in full force and effect.
16. This Agreement shall be effective and deemed delivered as of the last date first listed above.

IN WITNESS WHEREOF, the parties, through their authorized officers, have executed this Agreement as of the date first above written.

ADVANCED CARDIOVASCULAR SYSTEMS, INC.

By: /s/ Dana G. Mead, Jr.  
Name: Dana G. Mead Jr  
Title: President

GUIDANT CORPORATION

2/9/2007

By: /s/ Dana G. Mead, Jr.  
Name: Dana G. Mead, Jr.  
Title: President, Vascular Intervention

JOHNSON & JOHNSON

By: /s/ J.R. Hilton  
Name: J. R. Hilton  
Title: Assistant Secretary

CORDIS CORPORATION

By: /s/ Susan Morano  
Name: Susan Morano  
Title: V.P., New Business Development

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Exhibit A

**Schedule 1L**

[\*\*\*]

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**AMENDMENT**

This Amendment to the Master License Agreement and to the Distribution Agreement ("Amendment") is entered into by and between Cordis Corporation, Guidant Corporation, and Advanced Cardiovascular Systems, Inc. on this 24th day of November 2003 ("Effective Date").

**RECITALS**

CORDIS, GUIDANT, and ACS entered into a Master License Agreement dated April 3, 2000 ("Master License Agreement") that was further modified by an Addendum signed October 17, 2001, and by virtue of a modified license to the Patents signed December 21, 2001.

CORDIS, GUIDANT and ACS would now like to add other patent families to fall under the provisions of the Master License Agreement.

The parties further desire to avoid the possible time and expense of potential future dispute resolutions related to these added patent families.

CORDIS and ACS also entered into a Distribution Agreement (the "Distribution Agreement") effective April 3, 2000 by which ACS was to sell certain rapid exchange catheters to CORDIS.

CORDIS and ACS would further like to amend the Distribution Agreement to extend and continue supply of certain designated catheters to Cordis.

**TERMS**

The parties agree as follows:

2/9/2007



1. All words and phrases used herein shall have the meanings set forth in the Master License Agreement and the Distribution Agreement unless expressly stated otherwise.
2. "Fontirroche Patents" shall mean those Patents having in common the priority date or dates of those patents listed in Schedule "2".
3. "Rx Lau Patents" shall mean those Patents having in common the priority date or dates of those patents listed in Schedule "3".
4. Sections 2.9.1-2.9.2 are added to the Master License Agreement:
  - 2.9.1 Fontirroche Patents. CORDIS hereby grants to GUIDANT an irrevocable, non-exclusive, worldwide right and license (without the right to sublicense) to make, have made, use or sell or otherwise dispose of Licensed Products under the Fontirroche Patents and to practice processes and methods under the Fontirroche Patents, subject to the restrictions of Paragraph 2.15. The license granted pursuant to this paragraph [\*\*\*]
  - 2.9.2 Rx Lau Patents. GUIDANT hereby grants to CORDIS an irrevocable, non-exclusive, worldwide right and license (without the right to sublicense) to make, have made, use or sell or otherwise dispose of Licensed Products under the Rx Lau Patents and to practice processes and methods under the Rx Lau Patents, subject to the restrictions of Paragraph 2.15. The license granted pursuant to this paragraph [\*\*\*]
5. The Parties hereby waive any and all rights to seek past, present, and/or future damages, royalties, or compensation under the Fontirroche Patents or the Rx Lau Patents, as the case may be. These waivers include, but are not limited to, a full and complete waiver of any rights a Party might otherwise have to seek royalties, damages, or compensation from the other under any applicable Section of the Master License Agreement.
6. [\*\*\*]
7. The terms set forth in this Amendment are to be treated as confidential pursuant to Article V of the Master License Agreement and Article VIII of the Distribution Agreement.
8. The parties expressly agree that, except as specifically provided herein, the Master License Agreement, the Arbitration Agreement, and the Distribution Agreement, and all terms and provisions therein, shall remain in full force and effect in all respects. Nothing in this Amendment is intended to modify, supplement, or affect the parties' rights, obligations or licenses under their prior agreements unless expressly stated herein.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorized officers, effective as of the day and year first above written.

**CORDIS CORPORATION**

By: /s/ Susan E. Morano

Name: Susan E. Morano

Title: V.P., New Business Development

Date: \_\_\_\_\_

ADVANCED CARDIOVASCULAR  
SYSTEMS, INC.

By: /s/ Mark A. Murray

2/9/2007

Name: Mark A. Murray

Title: V.P., Finance

Date: \_\_\_\_\_

#### **GUIDANT CORPORATION**

By: /s/ Dana G. Mead, Jr.

Name: Dana G. Mead, Jr.

Title: President, Vascular Intervention

Date: \_\_\_\_\_

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#### Schedule 2 – Fontirroche Patents

[\*\*\*]

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#### Schedule 3 – Rx Lau Patents

[\*\*\*]

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#### Schedule 6

[\*\*\*]

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### **AGREEMENT**

This Agreement (“AGREEMENT”) is made effective as of the 20th day of December, 2001 (the “Effective Date”) by and between GUIDANT CORPORATION, an Indiana corporation, having a place of business at 111 Monument Circle, 29th Floor, Indianapolis, IN 46204, and its Affiliates (Guidant Corporation and its Affiliates, collectively referred to as “GUIDANT”); CORDIS CORPORATION, a Florida corporation, having a place of business at 14201 NW 60th Avenue, Miami Lakes, FL 33014, and its Affiliates (Cordis Corporation and its Affiliates, collectively referred to as “CORDIS”); NEOCARDIA, LLC, a Georgia limited liability company, and its Affiliates (NeoCardia, LLC and its Affiliates, collectively referred to as “NEOCARDIA”); and STEPHEN OESTERLE, MICHAEL D. DAKE, and BRUCE HEDGER (collectively referred to as “the OESTERLE GROUP”).

### **RECITALS**

- A. On May 4, 1994, the OESTERLE GROUP licensed certain patent rights to Omnitron International, Inc. (“OMNITRON”) pursuant to a license Agreement (“DAKE LICENSE”).
- B. On March 21, 1997, NEOCARDIA, OMNITRON, GUIDANT and ACS Delaware Corporation (a subsidiary of Guidant) entered into a Purchase Agreement (“NEOCARDIA AGREEMENT”) pursuant to which GUIDANT acquired certain assets, including the DAKE LICENSE.
- C. CORDIS has previously secured from GUIDANT certain rights under the DAKE-BRADSHAW PATENTS, pursuant to the Master License Agreement between and among GUIDANT and CORDIS effective April 3, 2000 (“MASTER LICENSE AGREEMENT”), subject to a pass-through royalty obligation to NEOCARDIA of [\*\*\*](“NEOCARDIA ROYALTY”) and to the OESTERLE GROUP of [\*\*\*] (“DAKE ROYALTY”).

2/9/2007

- D. Subject to certain conditions, the OESTERLE GROUP and CORDIS desire to convert the DAKE ROYALTY to a paid up license.

In consideration of the foregoing recitals and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged by each of the parties, GUIDANT, CORDIS, NEOCARDIA and the OESTERLE GROUP agree as follows:

#### 1. DEFINITIONS

Terms not otherwise defined in this AGREEMENT shall have the meanings set forth in the MASTER LICENSE AGREEMENT.

#### 2. AMENDMENT OF DAKE LICENSE AND MASTER LICENSE AGREEMENT

The DAKE LICENSE AND MASTER LICENSE AGREEMENT are amended so that the sublicense to the Dake patent granted by GUIDANT to CORDIS pursuant to the MASTER LICENSE AGREEMENT shall be fully paid up to the OESTERLE GROUP with respect to CORDIS's Checkmate system, and improvements thereto, and any other device developed using CORDIS research efforts or funds (without CORDIS acquiring any technology from a third party); provided, however that the foregoing do not use a beta radiation source. For the avoidance of doubt, the parties recognize that CORDIS's prior-announced X-ray system currently being developed is to be considered an "improvement" to the Checkmate system. Except as provided in the previous sentence, the DAKE ROYALTY shall continue to be owed to the OESTERLE GROUP with respect to LICENSED PRODUCTS. Notwithstanding anything in this AGREEMENT to the contrary, nothing in this AGREEMENT is intended to modify in any manner the NEOCARDIA ROYALTY owed by CORDIS to NEOCARDIA on LICENSED PRODUCTS.

#### 3. PAYMENTS

CORDIS shall pay within ten (10) days of the EFFECTIVE DATE a one-time lump sum payment to the OESTERLE GROUP of [\*\*\*], by wire transfer of immediately available funds. The arrangement for such wire transfer shall be communicated to Cordis as soon as practicable after the signing of this Agreement.

#### 4. RELEASE

Upon receipt of the aforementioned payments, the OESTERLE GROUP hereby release and forever discharge GUIDANT and CORDIS, and GUIDANT hereby releases and forever discharges CORDIS, from any and all obligation to pay the DAKE ROYALTY with respect to CORDIS' sales of products prior to the Effective Date.

#### 5. CONFIDENTIALITY AND NON-DISCLOSURE

Except to the extent that any party may otherwise determine disclosure of all or any part of this AGREEMENT is required by law, each party agrees to use reasonable efforts to hold confidential the existence of this AGREEMENT and the financial and economic terms of this AGREEMENT (including all amendments and modifications of such terms) (collectively, the "Confidential Information"), and not hereinafter directly or indirectly to divulge, disseminate or disclose any such Confidential Information. Further, and subject to the foregoing, each party shall use reasonable efforts to restrict distribution of copies of this AGREEMENT or any documents or other information related thereto only to such party's attorneys, accountants, financial advisors and employees having a need to know such Confidential Information (and only to the extent of such need). If any party is required by subpoena or other legal process of law to disclose any Confidential Information, the party required to make such a disclosure shall, when feasible, give notice to and cooperate with the other parties to allow any other party, at its expense, to resist disclosure of, or obtain an exemption from the requirement to disclosure, the Confidential Information. With respect to any party's reporting requirements to the public and/or the SEC, the parties agree that they shall each cooperate with one another to exclude from disclosing any of the Confidential Information that any other party desires not to be disclosed for competitive or other privacy reasons. The parties agree that before any written press release is made concerning this AGREEMENT they shall consult and cooperate with each other concerning the text of such press release.

#### 6. MISCELLANEOUS

2/9/2007

- 6.1. Governing Law. This AGREEMENT shall be interpreted, governed and construed in accordance with the laws of the State of New York, without regard to its choice of law rules.
- 6.2. Severability. The provisions of this AGREEMENT are intended to be severable. If any provision of this AGREEMENT shall be held invalid or unenforceable in whole or in part in any jurisdiction, such provision shall, as to such jurisdiction, be ineffective to the extent of such invalidity or enforceability without in any manner affecting the validity or enforceability thereof in any other jurisdiction or the remaining provisions hereof in any jurisdiction. In the event that the terms and conditions of this AGREEMENT have been materially affected, the parties will renegotiate the terms and conditions of this AGREEMENT to resolve any inequities.
- 6.3. Entire Agreement. This AGREEMENT, together with all other agreements referred to herein, shall constitute the entire agreement between the parties relating to the subject matter hereof and shall supersede all previous negotiations, commitments and writings relating thereto (other than the Confidentiality Agreements dated May 12, 1999 and July 8, 1998 between GUIDANT and Johnson & Johnson). This AGREEMENT shall not be modified or altered in any manner except by an instrument in writing executed by the parties.
- 6.4. Waiver. Any waiver must be in writing. A waiver of any breach of, or failure to enforce, any of the terms or conditions of this AGREEMENT shall not in any way affect, limit or waive a party's right at any time to enforce strict compliance thereafter with every other term or condition of this AGREEMENT.
- 6.5. Relationship of the Parties. Nothing in this AGREEMENT shall create or constitute a partnership or joint venture between the parties hereto, and other than as expressly provided in this AGREEMENT, no party shall enter into or have authority to enter into any engagement or make any representation or warranty on behalf of or pledge the credit of or otherwise bind or oblige the other party hereto.
- 6.6. No Admission. Neither the entering into this AGREEMENT, nor any provision hereof, shall be deemed as an admission by any party of any wrongdoing, or of the validity or invalidity of any patent or of any position taken or proposed to be taken by or against the party in any past, present, or future litigation, including but not limited to an admission by CORDIS that any of its current products are LICENSED PRODUCTS with respect to the DAKE-BRADSHAW PATENTS. The parties specifically agree that the consideration paid to the OESTERLE GROUP is in settlement of an arguable dispute to be resolved in an adversarial process.
- 6.7. Consultation with Counsel and Reliance. Each of the parties acknowledges that it has consulted with, or has had the opportunity to consult with, counsel of its choice, and that in executing this AGREEMENT it has not relied upon any statements, representations or agreements of any other person other than those contained herein.
- 6.8. Caption. Captions are inserted herein only as a matter of convenience and for reference, and in no way define, limit, or describe the scope of this AGREEMENT or the intent of any provision herein.
- 6.9. Counterparts. This AGREEMENT may be executed in counterparts, each of which shall be deemed an original, but both of which shall constitute one and the same instrument.
- 6.10. No Strict Construction. This AGREEMENT has been prepared with the participation of all parties, and shall not be strictly construed against any party.
7. Amendment of other Agreements. Nothing herein shall be construed to amend or modify in any manner any of the other terms of the DAKE LICENSE, NEOCARDIA AGREEMENT or MASTER LICENSE AGREEMENT, except as specifically stated in this AGREEMENT.

IN WITNESS WHEREOF, the parties hereto have executed this AGREEMENT as of the day and year first above.

#### **GUIDANT CORPORATION**

By: /s/ Mark A. Murray  
 Name: Mark A. Murray  
 Title: V.P., Finance

#### **CORDIS CORPORATION**

2/9/2007

By: /s/ Susan E. Morano  
 Name: Susan E. Morano  
 Title: V.P., New Business Development

#### NEOCARDIA, LLC

By: /s/ Richard Calfee  
 Name: Richard Calfee  
 Title: President

#### THE OESTERLE GROUP

By: /s/ Stephen Oesterle  
 Stephen Oesterle, for himself and  
 as the authorized representative  
 of Michael D. Dake and Bruce Hedger

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### ADDENDUM TO MASTER LICENSE AGREEMENT AND ARBITRATION AGREEMENT

This Addendum to Master License Agreement and Arbitration Agreement ("Addendum") is entered into by and between Cordis Corporation, Guidant Corporation, and Advanced Cardiovascular Systems, Inc. on this 17th day of October, 2001 ("Effective Date").

#### RECITALS

1. CORDIS, GUIDANT, and ACS entered into a Master License Agreement dated April 3, 2000 ("Master License Agreement") pursuant to which GUIDANT and ACS were granted, *inter alia*, license rights under the Pinchuk Patents.
2. Pursuant to the terms of the Master License Agreement, GUIDANT was required to pay CORDIS a royalty for any products that were found, via arbitration, to infringe any valid and enforceable claim of the Pinchuk Patents. The arbitration process was set forth in the April 3, 2000, Arbitration Agreement ("Arbitration Agreement") between CORDIS, GUIDANT, and ACS.
3. The parties wish to settle the current Cordis Balloon Arbitration and to avoid the possible time and expense of potential future arbitrations related to the Pinchuk Patents.

#### TERMS

The parties agree as follows:

1. All words and phrases used herein shall have the meanings set forth in the Master License Agreement unless expressly stated otherwise.
2. Within ten (10) business days from the date of execution of this Addendum, GUIDANT shall remit payment to CORDIS, via wire transfer, in the amount of [\*\*\*]. Upon receipt of such payment, CORDIS shall immediately terminate the ongoing Cordis Balloon Arbitration that was initiated pursuant to Section 2.1.2 of the Arbitration Agreement. CORDIS hereby waives any and all rights it might otherwise have to initiate additional arbitrations under Sections 2.1.2 or 2.1.3 of the Arbitration Agreement.
3. Section 2.3 of the Master License Agreement is modified in its entirety to read as follows:  
 2.3 Pinchuk Patents. CORDIS hereby grants to GUIDANT an irrevocable, non-exclusive,

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worldwide right and license (without the right to sublicense) to make, have made, use or sell or otherwise dispose of Licensed Products, under the Pinchuk Patents, and to practice processes and methods under the Pinchuk Patents, subject to the restrictions of Paragraph 2.15. The license granted pursuant to this paragraph shall be a paid-up license and any pass-through royalties payable in respect of past and future Net Sales of Licensed Products by GUIDANT (including Net Sales of the relevant products that occurred prior to the Effective date) shall be payable by CORDIS. Notwithstanding the foregoing[\*\*\*]

4. CORDIS hereby waives any and all rights to seek past, present, and/or future damages, royalties, or compensation from GUIDANT under the Pinchuk Patents. This waiver includes, but is not limited to, a full and complete waiver of any rights CORDIS might otherwise have to seek royalties, damages, or compensation from GUIDANT for infringement of the Pinchuk Patents under Sections 2.3, 2.10, or 2.12 of the Master License Agreement and/or Sections 2.1.2 or 2.1.3 of the Arbitration Agreement.
5. [\*\*\*]
6. The terms set forth in this Addendum are to be treated as confidential pursuant to Article V of the Master License Agreement.
7. The parties expressly agree that, except as specifically provided herein, the Master License Agreement, the Arbitration Agreement, and the Distribution Agreement, and all terms and provisions therein, shall remain in full force and effect in all respects. Nothing in this Addendum is intended to modify, supplement, or affect the parties' obligations under their prior agreements unless expressly stated herein.

So agreed:

CORDIS CORPORATION

By: /s/ Susan E. Morano  
 Name: Susan G. Morano  
 Title: V.P., New Business Development  
 Date: \_\_\_\_\_

ADVANCED CARDIOVASCULAR  
 SYSTEMS, INC.

By: /s/ Mark A. Murray  
 Name: Mark A. Murray  
 Title: V.P., Finance  
 Date: \_\_\_\_\_

GUIDANT CORPORATION

By: /s/ Keith E. Brauer  
 Name: Keith E. Brauer  
 Title: V.P., Finance and CFO  
 Date: \_\_\_\_\_

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EXHIBIT 31.1

**CERTIFICATION  
PURSUANT TO SECTION 302  
OF THE SARBANES OXLEY ACT**

I, Ronald W. Dollens, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Guidant Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and we have:
  - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - c) disclosed in this report any change in the registrant's internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
  - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 7, 2004

/s/ Ronald W. Dollens  
Chief Executive Officer

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EXHIBIT 31.2

**CERTIFICATION  
PURSUANT TO SECTION 302  
OF THE SARBANES OXLEY ACT**

I, Keith E. Brauer, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Guidant Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and we have:
  - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - c) disclosed in this report any change in the registrant's internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
  - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 7, 2004

/s/ Keith E. Brauer  
Chief Financial Officer

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EXHIBIT 32.1

**CERTIFICATION PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT**

In connection with the Quarterly Report of Guidant Corporation (the "Company") on Form 10-Q for the period ending March 31, 2004 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Ronald W. Dollens, Chief Executive Officer of the Company, certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 USC 1350), that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ Ronald W. Dollens  
Chief Executive Officer

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EXHIBIT 32.2

**CERTIFICATION PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT**

In connection with the Quarterly Report of Guidant Corporation (the "Company") on Form 10-Q for the period ending March 31, 2004 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Keith E. Brauer, Chief Financial Officer of the Company, certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 USC 1350), that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ Keith E. Brauer  
Chief Financial Officer

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**GUIDANT CORPORATION**

EXHIBIT 99

**Factors Possibly Affecting Future Operating Results**

From time to time, Guidant Corporation (the Company) publishes forward-looking statements relating to anticipated financial performance, business development (mergers, acquisitions, etc.), product development and regulatory approval timelines, intellectual property matters, market developments and similar matters. A variety of factors could cause the Company's actual results to differ materially from those projected, including the following:

1. Product development and production factors, including:
  - a. The difficulties and uncertainties inherent in new product development (including new products such as drug eluting stents), including products that appear promising during development but fail to reach the market or reach the market later than expected as a result of safety, performance or efficacy concerns, inability to obtain necessary regulatory approvals, unanticipated restrictions imposed on approved indications, excessive costs to manufacture or technological advances by competitors of the Company.
  - b. Unexpected safety, performance or efficacy concerns arising with respect to marketed products, whether or not scientifically justified, leading to product recalls, withdrawals or declining sales.
  - c. Unexpected interruptions of operations as a result of regulatory enforcement actions by the Food and Drug Administration (FDA) of the US, Japanese Ministry of Health, Labor and Welfare (MHLW), Medicines and Healthcare Products Regulatory Agency (MHRA) of the United Kingdom, or other regulatory authorities or the unavailability of necessary components or materials used in manufacturing the Company's products.
2. Litigation and other legal factors that could preclude commercialization of products, negatively affect the level of sales or profitability of existing products or otherwise affect the Company's reported results, including litigation of product liability matters, commercial, shareholder and patent litigation or regulatory enforcement actions (including any action with respect to the Company's Corporate Integrity Agreement with the Department of Health and Human Services), which could result in injunctions, the payment of royalties or other damages or penalties.
3. Competitive factors, including:
  - a. The ability of the Company to obtain intellectual property rights sufficient to protect its products or the acquisition of patents by competitors that prevent the Company from selling a product or including key features in the Company's products.
  - b. The introduction of new products or therapies by competitors, including competitive stent launches in Japan, as well as the new entrant in cardiac resynchronization therapy in the US.
  - c. Scientific or medical developments that render the Company's existing products less competitive.
4. Domestic and international governmental factors including changes to laws and regulations, policies and judicial decisions that affect the regulation and reimbursement of medical devices, product liability, healthcare reform or tax laws.
5. Healthcare industry factors, including increased customer demands for price concessions, reductions in third-party (Medicare, Medicaid and other governmental programs, private healthcare insurance and managed care plans) reimbursement levels or refusals to provide reimbursement for procedures using the Company's products. Customers may limit the number of manufacturers or vendors from which the customers will purchase products, which can result in the Company's exclusion from large hospital system, integrated delivery network or group purchasing organization contracts.

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6. Internal factors, such as the loss of key employees and changes in business strategies.
7. The impact of restructuring and business combinations, including the integration of acquired businesses.
8. General economic factors, including changes in foreign currency exchange rates, interest rates and inflation.
9. Other factors beyond the control of the Company, including earthquakes (particularly in light of the fact that the Company has significant facilities located near major earthquake fault lines), floods, fires, explosions or acts of terrorism or war, the outcomes of which may not be covered by insurance.

The Company does not undertake to update its forward-looking statements.

The Company's Annual Report on Form 10-K further describes risks associated with manufacturing, patents, competition, regulation, third-party reimbursement and related matters.

2/9/2007

# EXHIBIT 46

REDACTED



# EXHIBIT 47

**Patterson Belknap Webb & Tyler** LLP

1133 Avenue of the Americas New York, NY 10036-6710 212.336.2000 fax 212.336.2222 www.pbwt.com

Rosa E. Son  
(212) 336-2388

February 1, 2007

**BY ELECTRONIC MAIL AND FACSIMILE**

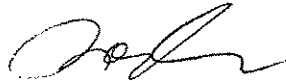
Tracey C. Allen, Esq.  
Wilmer Hale  
1875 Pennsylvania Avenue, NW  
Washington, D.C. 20006

Re: **Wyeth v. Cordis -- Civil Action No. 06-663 (SLR)**

Dear Tracey:

I write in response to your January 30, 2007 letter to me. Cordis stipulates that the tax returns produced bearing Bates numbers CWY000436-795 are true and correct copies of (1) the tax returns filed by Cordis in New Jersey and (2) the pro forma tax returns provided to Johnson & Johnson by Cordis for inclusion in the consolidated returns filed by Johnson & Johnson in Florida. The information contained in these documents was accurate at the time the documents were prepared.

Very truly yours,



Rosa E. Son

# EXHIBIT 48

REDACTED

# EXHIBIT 49

REDACTED



# EXHIBIT 50

REDACTED

CERTIFICATE OF SERVICE

I, the undersigned, hereby certify that on February 20, 2007 I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing(s) to the following:

Richard L. Renck  
Ashby & Geddes  
rrenck@ashby-geddes.com

I also certify that copies were caused to be served on February 20, 2007 upon the following in the manner indicated:

**BY HAND**

Lawrence C. Ashby  
Steven J. Balick  
Richard L. Renck  
ASHBY & GEDDES  
222 Delaware Ave.  
P.O. Box 1150  
Wilmington, DE 19899

**BY EMAIL**

Gregory L. Diskant  
*gldiskant@pbwt.com*  
Michael J. Timmons  
*mjtimmons@pbwt.com*  
Irena Royzman  
*iroyzman@pbwt.com*  
Patrick S. Almonrode  
*palmonrode@pbwt.com*  
Rosa E. Son  
*reson@pbwt.com*  
PATTERSON, BELKNAP, WEBB & TYLER LLP  
1133 Avenue of the Americas  
New York, NY 10036

/s/ Richard J. Bauer (#4828)  
Richard J. Bauer (#4828)